

Attorney Docket No.: **KBI-0016**
Inventors: **Ranganathan, Natarajan**
Serial No.: **10/676,558**
Filing Date: **September 30, 2003**
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REMARKS

Claims 1-5 are pending in the instant application. Claim 5 has been withdrawn from consideration and canceled. Claims 1-4 have been rejected. Claim 1 has been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Election/Restriction

The restriction requirement placing the claims into Groups I and II has been deemed proper and made final. Claim 5 is withdrawn from further consideration. Accordingly, Applicant is canceling claim 5 without prejudice, reserving the right to file continuing applications for the canceled subject matter.

II. Objection to the Specification

The Examiner has objected to the specification for failing to identify the current status of the parent cases. Accordingly, Applicant has amended the specification to update the status of the priority documents. Withdrawal of this objection is therefore respectfully requested.

III. Rejection of Claims under 35 U.S.C. §102

Claim 1 has been rejected under 35 U.S.C. 102(b) as being anticipated by Cavaliere Vesely et al. (U.S. Patent No. 5,716,615), Morelli et al. (U.S. Patent No. 5,709,857) or Araki et al. (U.S. Patent No. 5,741,494).

The Examiner suggests that Cavaliere Vesely et al. teach compositions comprising *Streptococcus thermophilus*, *Lactobacillus* and/or *Bifidobacteria* (probiotics which reduce urea when

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ingested) wherein the compositions absorb or reduce endogenous toxic substances.

It is further suggested that Morelli et al. teach a composition comprising *Lactobacillus* (a probiotic which reduces urea when ingested).

The Examiner suggests that Araki et al. also teaches compositions comprising *Bacillus*, *Lactobacillus* and/or *Bifidobacterium* species (probiotics which reduce urea when ingested).

It is suggested that while the cited references do not teach the claimed function and use of the compositions, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such disclosed use is inherent in the reference composition. Applicant respectfully disagrees with this rejection.

The compositions of Cavaliere Vesely et al. are disclosed for use in treating gastrointestinal disorders and hypercholesteremia. Such compositions comprise several different bacteria including *Streptococcus thermophilus*, *Lactobacilli* and *Bifidobacteria* (column 3, lines 1-12), and can further include excipients such as maltodextrin, microcrystalline cellulose, maize starch, levulose, lactose, and dextrose (column 3, lines 37-40); and additives such as sodium citrate, calcium carbonate, calcium dihydrogen phosphate, and gelatin (column 3, lines 44-47). The compositions of Morelli et al. contain *Lactobacillus* strains for the treatment or prophylaxis of gastrointestinal pathologies (column 2, lines 54-64). Akari et al. et al. teach compositions comprising *Bacillus* (e.g., *Bacillus subtilis* Natto, *Streptococcus faecalis*, *Clostridium butyricum*, *Lactobacillus*

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lactis and *Bifidobacterium bifidum*) in combination with egg white and garlic as immunopotentiative and infection-protective agents. None of the cited references teach enteric dialysis using a *Streptococcus thermophilus* probiotic bacterium which reduces the urea concentration when ingested by a host.

In contrast, the instant specification teaches a composition for reducing urea and urea-waste products thereby reducing the burden on ailing kidney (page 10, lines 31-35). Such a composition comprises a probiotic bacterium such as *Streptococcus thermophilus* in combination with one or more adsorbents including locust bean gum with a specific affinity for creatinine and urea; activated charcoal with a specific affinity for creatinine, guanidines, phenol, indican and middle molecular weight undefined components; and water adsorbents such as psyllium fiber, guar gum and locus bean gum. See page 10, lines 10-27). Accordingly, to clarify the instant composition, Applicant has amended claim 1 to recite that the composition comprises a *Streptococcus thermophilus* probiotic bacterium and at least one adsorbent. Because the cited references are silent to the combination of a *Streptococcus thermophilus* and at least one adsorbent, these references fail to anticipate the instant invention. It is therefore respectfully requested that this rejection be withdrawn.

IV. Rejection of Claims under 35 U.S.C. §102/103

Claims 1-4 have been rejected under 35 U.S.C. 102(b)/103(a) as being unpatentable over Cavaliere Vesely et al. It is suggested that while this reference does not specifically teach the claimed strains of *S. thermophilus*, the composition appears

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to be the same as that of the claim and therefore anticipates it. It is further suggested that even if the reference does not anticipate the claimed subject matter, the claim is rendered obvious over Cavaliere Vesely et al. because the reference clearly teaches compositions comprising *S. thermophilus* which reduce and/or absorb endogenous toxins (or urea). The Examiner suggests that it would have been obvious to one of ordinary skill in the art to use any strain of *S. thermophilus* in the composition of Cavaliere Vesely et al., with a reasonable expectation of successfully obtaining an effective composition for reducing endogenous toxins. Applicant respectfully disagrees.

As indicated *supra*, Cavaliere Vesely et al. fails to teach or suggest a composition comprising a *Streptococcus thermophilus* probiotic bacterium and at least one adsorbent. Because this reference fails to teach each and every limitation of the amended claims (MPEP 2131 and 2143.03), this reference does not anticipate nor make obvious the instant invention. It is therefore respectfully requested that this rejection be withdrawn.

V. Double Patenting

Claim 1-4 have been *provisionally* rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5 and 13 of copending Application No. 10/803,211.

Claims 1-4 have been *provisionally* rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 8, 10 and 11 of copending Application No. 10/689,359.

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Claim 1-4 have been *provisionally* rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-2 of copending Application No. 10/936,262.

Applicant respectfully requests that these rejections be held in abeyance until allowable subject matter has been identified in copending Application Nos. 10/803,211; 10/689,359; and 10/936,262.

Claim 1-4 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,706,287.

Claim 1-4 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,706,263.

Applicant has filed herewith a terminal disclaimer in compliance with 37 CFR 1.321(c) and therefore respectfully requests that these rejections be withdrawn.

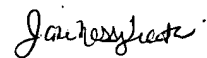
VI. Conclusion

The Applicant believes that the foregoing comprises a full and complete response to the Office Action of record.

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Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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Date: **July 28, 2005**

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